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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jacques Marie Rene Jan Huyghe

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EXAMINER

YANG, ANDREW

ART UNIT

PAPER NUMBER

3775

NOTIFICATION DATE

DELIVERY MODE

02/03/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/564,518	Applicant(s) HUYGHE ET AL.	
	Examiner ANDREW YANG	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11,21-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11,21-27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicant's amendment filed on November 22, 2010.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 21, 24-27, and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al. (U.S. Patent No. 5458643) in view of Coury et al. (U.S. Patent No. 7008635) and further in view of Stubstad et al. (U.S. Patent No. 3867728).

Oka et al. discloses a prosthesis having a flexible portion 22 and at least one less flexible portion 4. The flexible portion is formed of a hydrogel. The less flexible portion can be provided on the upper/lower/inner sides of the flexible portion (Figures 3a-3e) and serves as an endplate. The hydrogel 22 is PVA and has swelling characteristics comparable to those of a natural disc. The device is intended to be implanted in a human or animal (Figure 4).

Oka et al. fails to disclose the hydrogel containing chopped fibers and charged groups. Coury et al. teaches using hydrogels to form intervertebral disc implants and that fibers can be added to the hydrogel to improve their toughness under load and shear (Column 9, Lines 48-51). Coury et al. also discloses the hydrogels to have charged groups (Column 2, Lines 15-17) so that the hydrogel has suitable mechanical

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properties of toughness and strength while still maintaining the advantage of biocompatibility and lubricity. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Oka et al. with the hydrogel containing fibers in view of Coury et al. to improve the toughness of the hydrogel under load and shear and to maintain biocompatibility and lubricity. Furthermore, it would be obvious to have chopped fibers as fibers are generally formed of a single strand and require cutting or chopping to a size suitable for the required application.

Oka et al. also fails to disclose fibers wound around and encompassing the whole of the flexible portion and at least one less flexible portion. Stubstad teaches an implant having a flexible portion and at least one less flexible portion 11. The less flexible portion and the flexible portion have a fiber 29 that is wound around and encompass the whole of the flexible portion and at least one flexible portion (Figure 1). The fiber 29 provides a means for securely anchoring the pieces together thereby having a low elasticity modulus. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Oka et al. with fibers wound around and encompassing the whole of the flexible portion and at least one less flexible portion in view of Stubstad to securely anchor the separate pieces together.

Regarding claims 8-10, it would have been obvious to one skilled in the art at the time the invention was made to construct the flexible portion of Oka et al. as modified by Coury et al. and Stubstad having the claimed thicknesses and the percentage of fibers, since it has been held that where the general conditions of a claim are disclosed in the

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prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 32 and 33, it would have been obvious to one skilled in the art at the time the invention was made to construct the device of Oka et al. as modified by Coury et al. and Stubstad et al. with fibers capable of absorbing hydrogel monomers or made of polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claims 24-27, 29 and 30, it is noted that the Applicant is claiming an article of manufacture and not the process of forming/making the device, accordingly, the manner in which the device is formed, i.e. winding or knitting, slicing, is given little weight as long as the final product is shown. The burden is upon the applicant to come forward with evidence establishing an unobvious difference between the prior art and the current application. In re Marosi, 218 USPQ 289 (Fed Cir. 1983). Furthermore, it can be seen that the fiber 29 of Stubstad is wound around the implant

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al. (U.S. Patent No. 5458643) in view of Coury et al. (U.S. Patent No. 7008635), Stubstad et al. (U.S. Patent No. 3867728) and further in view of Bao (U.S. Patent No. 5047055) and Stoy (U.S. Patent No. 6264695).

Oka et al, Coury et al. and Stubstad et al. disclose the claimed invention except for reducing the volume of the implant prior to insertion by soaking the implant in a salt bath. Bao et al. teaches a hydrogel implant for an intervertebral disc that is implanted in

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a human (Column 7, Lines 30-40). Prior to implanting the volume of the prosthesis is reduced by dehydration so as to reduce the size of the implant for insertion (Column 7, Lines 55-60). It would have been obvious to one skilled in the art at the time the invention was made to reduce the size of the device of Oka et al. as modified by Coury et al. and Stubstad et al. by dehydration prior to inserting further in view of Bao et al. in order to reduce the size of the implant for insertion.

Bao et al. fails to disclose dehydrating by immersing the implant in a hypertonic salt bath. Stoy teaches using a salt bath to reduce the volume of the prosthesis in order to not completely dehydrate the implant and avoiding making the implant brittle for insertion (Column 13, Lines 10-15). It would have been obvious to one skilled in the art at the time the invention was made to reduce the volume of the device of Oka et al. as modified by Coury et al., Stubstad et al. and Bao et al. by using a salt bath further in view of Stoy in order to prevent the implant from becoming brittle for insertion.

Response to Arguments

In response to Applicant's argument that Oka fails to disclose a hydrogel which is ionized, the Examiner has addressed this newly added limitation in the rejection above using Coury.

In response to Applicant's argument that the references in combination fail to disclose fibres wound around and encompassing the whole of the flexible portion and the less flexible portion, the Examiner respectfully disagrees. Stubstad teaches the limitation. As seen in figure 2 of Stubstad, fibers 21 are wound around the top and

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bottom endplates and in figure 1 a fiber 29 is wound around the periphery of the implant joining the two endplates and the central portion into one implant. Fiber 29 and fibers 21 combine to form a network of fibers that are wound around and encompass the entire implant. Furthermore, it can also be considered that the fiber 29 alone encompasses the whole of the flexible portion and at least one less flexible portion. Encompass as defined by dictionary.com is to form a circle about. Thus the fiber 29 forms a circle about the two endplates and the central member.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/
Examiner, Art Unit 3775

/EDUARDO C. ROBERT/
Supervisory Patent Examiner, Art Unit 3733